



Military Medical Research News

Vol. 4, Issue 10 ■ October 2017

Researchers detail diverse causes for prostate cancer Recent findings illuminate disease in Caucasians, African Americans

by Paula Amann

Imagine self-driving cars with two big problems. First, the owner's manuals don't identify the accelerator or the brakes. What's more, different models require different instructions, yet only one manual is available for all.

That analogy sums up knowledge of the most common male cancer in 1993 when Shiv Srivastava began its study.

"We didn't know what caused prostate cancer," said Srivastava, in an interview at the Center for Prostate Disease Research (CPDR) in Rockville, Maryland, where he is now codirector. Nor did scientists grasp that, at the cellular and genetic level, those causes may take different forms in men of different racial and ethnic backgrounds.

"Up until now, we'd been suspecting race- and ethnicity-associated genomic differences in prostate cancer, but we didn't have definitive data," said Srivastava, who directs the Basic Science Research Program at CPDR. He is also a professor in the Department of Surgery at the Uniformed Services University of the Health Sciences (USU).

Yet, Jason Sedarsky and Michael Degon, both former urologists at Walter Reed National Military Medical Center, Srivastava and CPDR associate director, Albert Dobi, found just that. Their 2017 study in *Nature Reviews/Urology*, looked at global research as well as their own.



Shiv Srivastava, front, codirector of the Center for Prostate Disease Research, and Albert Dobi, CPDR's associate director, view slides of prostate cancer tumors. Magenta stains reveal the presence of ERG, a gene linked to the disease. Blue stains of cell nuclei show signs of genetic damage. (Photo by Paula Amann)

Prostate cancer's biological causes include ERG, an oncogene or cancer "accelerator" gene, which Srivastava called the "most validated" gene defect for the disease.

"ERG in model systems, in the lab, in cell lines, and in transgenic mice shows functions which confer cancer properties to cells," Srivastava said.

ERG generally has its highest prevalence in prostate tumors from males of European descent. At the molecular level, however, the disease

See CANCER, page 8



Some 20 people crowd Room 1369 of Building 8 on Sept. 19 for a presentation in the new series, Lunch and Learn: Research 2.0. See stories on this and other recent department events on pages 5, 10 and 11. (Photo by John Fadoju)



DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs at Walter Reed National Military Medical Center supports research in the National Capital Region.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other programs across our region.

MILITARY MEDICAL RESEARCH NEWS

Supervising editor

Army Col. Ann Nayback-Beebe

Contributing writers

Wendy Gilbert

Editor

Paula Amann

Layout and photo associate

John Fadoju

This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). ***Please send any timely information by the 15th day of the prior month for the following month's issue.***

Send your ideas or photos to paula.m.amann.ctr@mail.mil.

Not on our email list? Don't miss an issue. Please drop us an email, and we will add you to our distribution list.

RESEARCH FIRST STEPS

Our research protocol specialists (formerly protocol navigators) are available to help you start the process and assist you with your submission. To make an appointment with a protocol specialist, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

RESEARCH ROUNDTABLE SCHEDULE

Walter Reed Bethesda, America Building (Building 19), Room 2301

- ♦ Tuesday, Oct. 17, 1200-1300
Diane Beaner, Non-Compliance in Human Subjects Research
- ♦ Tuesday, Nov. 21, 1200-1300
Sanjur Brooks, How to Craft a Data-Sharing Agreement

CORRECTION

Harvey Duze of the Strategic Communications Department took the group photo on page 7 of our September issue for the story on the colors ceremony honoring winners of the Navy-wide research competition. Thanks, Mr. Duze!

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EIRB TIP OF THE MONTH Details That Speed Your Submission

When completing forms, please complete every section. If a section is not applicable, clearly state this (e.g., N/A). Your action will keep your submission to the Electronic Institutional Review Board (EIRB) from being returned as incomplete.

Up for continuing review? Please review last year's continuing review report. This will ensure accuracy when reporting on current research. For example, ensure "total numbers" (study participants screened, enrolled or withdrawn; or records reviewed retrospectively) reported for the current year reflect the numbers in last year's continuing review.

Detail project changes. In the Modification Form section 2.7, explain why your team is making modifications. Also, please list the actual changes to the research or research documents.

Help your reviewers help you. Please follow the EIRB's User Guide (Human) section, "Modifying a Consent or Other Protocol Document," when revising an existing document in your protocol. Doing this will allow reviewers to use EIRB's Compare Tool feature, which could speed the review of your submission.

Thanks for your patience and for all you do at Walter Reed Bethesda.

**—Wendy Gilbert,
Institutional Review Board manager**



COMMAND CORNER

Scientific review: A crucial step to research

All medical research should be conducted under a carefully constructed and meticulously planned research protocol. To assure appropriate research, every research protocol must undergo three distinct but interactive and interrelated reviews: the scientific review, the administrative review and the ethical review.

Scientific review is at the heart of a research protocol and critical to both its validity and its ethical basis. Without an adequate scientific review that assures appropriate thought is given to the background, methods, analysis and subject selection, it is unethical to conduct this research.

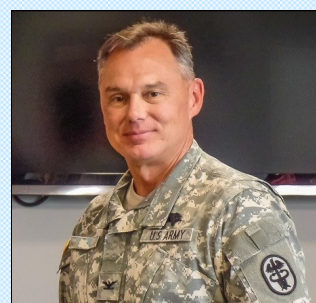
In 2014, we started the transition from a centralized to a decentralized scientific review. The reasons for this were many, but a critical one is that the scientific review is undertaken by an expert in the field rather than a person who knows only a single field or understands the scientific method.

Today, every service or department chief who signs off on a research protocol is certifying to the Institutional Official, Navy Capt. Mark Kobelja, that an adequate scientific review was undertaken and the results of that review were considered by the principal investigator.

The service or department chief do not have to do the review themselves. They can assign someone in their service or department to undertake this task.

Regardless of who actually does the scientific review, the Institute of Medicine provides a detailed checklist for an adequate one. Additionally, the Department of Research Programs is standing by to assist anyone in this critical task. Just call or stop by any time.

Together, we can assure that the research undertaken here at Walter Reed National Military Medical Center is the best in the entire Military Health System.



Army Col. Peter J. Weina
(Archival photo by John Fadoju)

Col. Peter J. Weina
Director, Department of Research Programs

GETTING STARTED WITH THE INSTITUTIONAL REVIEW BOARD AT WALTER REED BETHESDA

A convened IRB panel meets twice a month, with actions assigned based on submission deadlines.

Submission deadlines are the dates that the IRB receives a submission with all administrative, scientific and any other required pre-reviews *already done*. Please work with a research protocol specialist and refine your project in time to make these deadlines.

Expedited actions have no submission deadlines, because the IRB reviews them independently of the convened meeting schedule.

However, please follow these deadlines to help build our IRB agenda for the rest of 2017. Thank you for your cooperation.

Convened IRB Meetings	Submission Deadlines (Time: 1600)
October 12	September 28
October 26	October 12
November 9	October 26
November 16	November 2
December 14	November 24
December 21	December 7



ANNOUNCEMENTS

Series sheds light on clinical trials, technology transfer

Please put Lunch and Learn: Research 2.0 on your calendar for noon to 1 p.m. on the second and fourth Wednesdays. On Oct. 11, the new series offers a webinar on pragmatic clinical trials. On Oct. 25, research attorney Martin Hindel will present “Introduction to Technology Transfer.” Please find details on back cover

Research funding opportunities abound

Lisa Potts, grant writer at the Department of Research Programs, is alerting research teams to these upcoming deadlines:

▪ Congressionally Directed Medical Research Programs

FY17/18 Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) The Complex Traumatic Brain Injury Rehabilitation Research – Clinical Research Award (CTRR – CRA) supports applied and translational research to advance development of knowledge and products to rehabilitate and restore function after traumatic brain injury. The Complex Traumatic Brain Injury Rehabilitation Research – Clinical Trial Award (CTRR – CTA) supports clinical trials to advance the development of knowledge and products for rehabilitation and restoration of function following traumatic brain injury in service members, veterans, and other individuals with TBI. *Pre-Application Submission Deadlines: 5:00 p.m. Eastern time (ET), October 11, 2017*

FY17 Orthotics and Prosthetics Outcomes Research Program (OPORP) challenges the scientific community to address which orthotic and prosthetic devices generate the best patient outcomes. *Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), October 20, 2017*

FY17 Hearing Restoration Research Program (HRRP) – Translational Research Award supports preclinical translational research that will accelerate movement of promising initiatives on hearing restoration into clinical applications. Focused Research Award supports functional hearing restoration research that develops and validates assessment techniques and treatment methods using patient-centric outcomes to identify potential predictive indicators for successful treatment of functional auditory system deficits. *Pre-Application (Letter of Intent): October 25, 2017, 5:00 p.m. ET*

▪ Defense Health Program

The Department of Defense Psychological Health and Traumatic Brain Injury Research Program will be seeking applications and proposals on behavioral and psychological health. Watch for award announcements this month at Grants.gov. The program is interested in research that examines the efficacy and effectiveness of peer-to-peer support tools to translate and integrate content into the everyday routines of service members to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors. □

TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department or join our monthly classes. We have only eight spaces per class, so sign up now!

Your Monthly Class

Find it in Heroes Building (Building 5), fourth floor:

- Oct. 10, 2 p.m., Computer Classroom 1 (Room 4010)
- Nov. 14, 3 p.m., Computer Classroom 2 (Room 4011)
- Dec.



Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.

You belong in the CITI. Start training today!



Silberberg sees dark clouds over medical research

Shortcomings in design rigor, reporting, publication bias flagged

by Paula Amann

Shai Silberberg, director of research quality at the National Institute of Neurological Disorders and Stroke, turned his title on its head while addressing a small audience at Walter Reed National Military Medical Center on Sept. 25.

His talk, “Assuring a Bright Future for Biomedical Research,” signaled serious challenges facing the field, starting with the rigor of many studies.

Even prestigious journals have published research that fails basic tests, Silberberg alleged.

A 2006 study by Hackam and Redelmeier reviewed 76 “high impact” articles on animal trials, each of which drew more than 500 citations. Yet, only 20 percent of the articles reported “blinding” data, and a paltry 12 percent randomized subjects.

“Researchers have to rush studies to publication,” said Silberberg.

He lamented the “paper money” chase that drives scientists to churn out papers in order to win grant support.

Also pervading the field, said Silberberg, is the experimental bias that stems from the human tendency toward “unconscious selection” of evidence that supports the researcher’s hypothesis.

He cited mention of this problem by Thomas Chrowder Chamberlin, a geologist, as far back as 1897.

What’s more, journals show “publication bias” by largely favoring papers on

experiments that prove a hypothesis over those that debunk one, Silberberg said.

All of these trends are converging amid a dramatic rise in the number of medical studies, he said. For instance, said Silberberg, English-language publications listed in the



Shai Silberberg shares concerns about biomedical research at a talk on Sept. 25, cohosted by the Department of Research Programs and the Health Services Research Program at Uniformed Services University. (Photo by Paula Amann)

PubMed database climbed from 84,617 in 1964 to 1,118,710 in 2014, a thirteen-fold increase.

‘Change will happen, but it’s going to be slow. There are innovative ways to change the culture.’

— Shai Silberberg, director of research quality, National Institute of Neurological Disorders and Stroke, on transforming the ‘publish or perish’ culture of today’s biomedical research.

Silberberg has been working to boost the quality of medical research. In 2012, he was one of 36 scientists to join “A call for transparent reporting to optimize the predictive value of preclinical research” in the high-profile journal, *Nature*.

In the five years since that opinion piece appeared, the journal has strengthened its

editorial guidelines, and the National Institutes of Health have instilled more rigor in their grant reviews.

“Change will happen but it’s going to be slow,” said Silberberg. “There are innovative ways to change the culture.” □



Joint Pathology Center, deemed ‘national treasure,’ turns 100

By Paula Amann

Military brass in dress uniform joined the staff of national lawmakers and a medical entrepreneur to mark the centennial of the Joint Pathology Center Tissue Repository (JPC) on Sept. 14 in Silver Spring.

The center, nestled in the Forest Glen Annex, holds some 32 million tissue samples, 55 million glass slides and 750,000 “wet tissue” specimens. These medical data points range from the 1918 Spanish flu to decades of tissue samples from military working dogs.

“I cannot stress enough the national treasure this is,” said Navy Vice Adm. Raquel C. Bono, keynote speaker at the Sept. 14 ceremony for JPC, citing its description by the former Institute of Medicine (Health and Medicine Division) at the National Academies of Sciences.



Vice Adm. Raquel C. Bono, director of the Defense Health Agency, addresses the audience at a Sept. 14 ceremony marking the 100th anniversary of the Joint Pathology Center Tissue Repository.



Dr. Andrew Beck, president and CEO of Path AI, describes his partnership with the Joint Pathology Center, which uses artificial intelligence to help pathologists diagnose diseases such as pancreatic cancer. (Photos by John Fadoju)

“The brain trust and the intellectual capital it took to build this [are] staggering,” she said.

Bono joined a roster of speakers including Army Col. Clayton D. Simon, the JPC director; Joan D. Kleinman, state director for Maryland Sen. Chris Van Hollen; Jennie Foont from the office of Maryland Rep. Jamie Raskin; and Dr.

diagnose such diseases as pancreatic cancer. Their early findings show improved accuracy in diagnosing this often-lethal disease.

The results, Beck said, suggest the power of digitizing to advance medicine and save lives.

“AI plus pathologist is going to be more powerful than pathologist alone,” Beck said.

While looking to the medical future, Simon remains awed by the scope of the JPC collection, which includes medical specimens from the 1880s preserved in whiskey.

“It’s history,” Simon said of the sprawling tissue bank he oversees. “It’s amazing what we actually have here.”

Andrew Beck, president and CEO of Path AI.

In an April 2011 report from the Joint Task Force of the National Capital Region, the Asterand Bioscience corporation assessed the value of JPC’s collection at \$1.4 billion and, with improvements, \$3.3 billion.

Today’s medical entrepreneurs are already mining this resource.

Over the past year, for example, Beck has been applying artificial intelligence (AI) to JPC samples in an effort to enhance diagnosis.

He is working with Simon and Dr. Teri Franks, a pathologist, to devise a digital tool to help

See TREASURE, page 7



TREASURE, from page 6

Army Col. Derron A. Alves, master of ceremonies and director of veterinary pathology at JPC, noted the vision of its founders in creating a resource for military and civilian clinicians alike. JPC's "pairing of a centralized repository with subspecialty pathology" remains as relevant today as a century ago, Alves said.

Just this year, research on 1960s glass slides of human pulmonary melioidosis found promising vaccine targets, the JPC reports.

This bacterial disease is found in southeast Asia and northern Australia, including places where service

members deploy. Yet, a future vaccine would benefit both civilian and military patients around the world.

"What military medicine can bring to the rest of medicine is longitudinal data," said Bono in her remarks.

She noted that the armed services collects "cradle to grave" data on service members. These research resources, she said, can inform Big Data, part of the future of medicine. □



From left, Adm. David Lane, director, National Capital Region Medical Directorate; Vice Adm. Raquel Bono; Army Col. Clayton Simon, director, Joint Pathology Center; Joan Kleinman, state director in the Office of Sen. Chris Van Hollen; and Army Col. Peter Weina, director, Department of Research Programs, take in the center's centennial ceremony Sept. 14. (Photo by John Fadoju)

Interested in data analysis?

**Let the biostatistics team at the Department of Research Programs help.
With two weeks' notice, we can lecture on many topics for you and five or more people:**

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?

Contact Francois Tuamokumo, Ph.D., at francois.tuamokumo.civ@mail.mil



CANCER, from page 1

looks different for African-American patients and those from some Asian nations, such as China and Japan.

“What we found was [that] there were two- to threefold differences in ERG between Caucasian and African-American men with prostate cancer,” said Srivastava. Prostate cancer patients from Japan, Korea and China showed the lowest occurrence of ERG.

Also this year, Jennifer Cullen, CPDR’s director of epidemiology, and 22 colleagues from the center and its partners looked at ERG oncoprotein expression, race, body mass index and cancer relapse after radical prostatectomy in a large sample – 930 patients – from Walter Reed Bethesda.

Their study in European Urology Focus confirmed distinct differences in the presence of ERG between Caucasian and African-American men, who show lower prevalence of this oncoprotein.

As for prostate cancer’s “braking system,” PTEN and PMEPA are tumor-suppressor genes for cancer development. The latter, discovered at CPDR around 2000, serves to curb the function of a receptor for androgen, the male hormone.

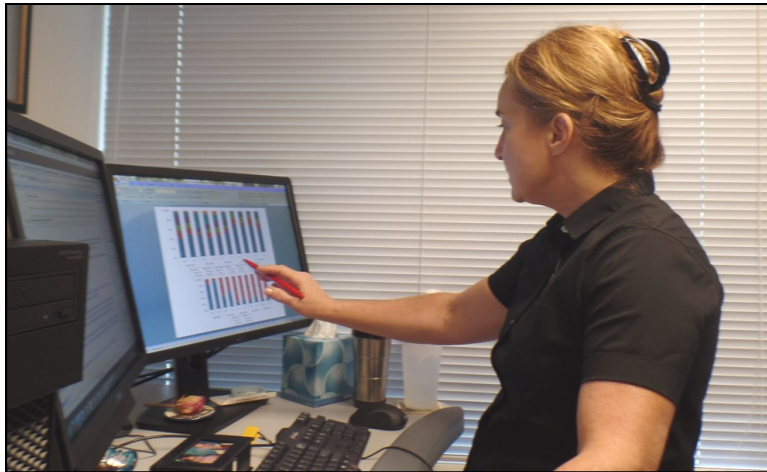
“The moment we lose the brake, the male hormone accelerators start,” Dobi said, noting that the absence of PTEN or PMEPA can activate cancer cell growth.

As for the presence of these braking systems, differences emerge between men of different backgrounds. In the case of PTEN, Sedarsky and his colleagues found it deleted in a half to two-thirds of Caucasian patients with prostate cancer.

Among African-American males, LSAMP, a missing suppressor gene on chromosome 3, correlates with faster disease progression, according to a 2015 study by Gyorgy Petrovics of CPDR and 33 researchers worldwide.

Meanwhile, prostate cancer’s biochemistry may be even more complex than thought. In a new twist, Cullen et al. found a strong link between tumors without ERG and more aggressive prostate cancer in Caucasian men.

Study by study, military medicine is helping to fill in the picture of prostate cancer, say Srivastava and Dobi. An equal-access health care system, coupled with a diverse set of patients (one third of them African American), has offered researchers an ample window on the disease.



Jennifer Cullen, director of epidemiology research at CPDR, looks at trends in treatment for high-risk prostate cancer patients, examining differences between Caucasian and African-American patients. (Photo by Paula Amann)

“It gives us a unique opportunity at Walter Reed [Bethesda] studying this question: race-associated factors in cancer,” Srivastava said.

Asked about research goals, Cullen cited as her “biggest looming questions” the reason why few patients die of prostate cancer and what patterns may occur in families with multiple cancers.

A common component of CPDR’s recent studies is a broad network of partners — from Isabell Sesterhenn of the Joint Pathology Center in Silver Spring to the Fred Hutchinson Cancer Research Center in Seattle.

As cancer researchers race to expand life-saving knowledge, the U.S. population is becoming more diverse, Dobi noted. What’s more, intermarriage between people of varied backgrounds might one day make “self-reported” race or ethnicity hard to gauge.

“At some point in the United States, the self-declared ethnicity will have no meaning,” Dobi said.

All the more reason, say researchers, to build a future of personalized medicine, where genetic profiles may open up new choices for patients.

“It may be far off right now, but we’re getting there,” Srivastava said. “The important thing is it will help us diagnose and treat patients better.” □



More knowledge, more choices

Research advances in prostate cancer broaden options for patients

by Paula Amann

Diplomas cram the office walls of Army Col. (Dr.) Inger Rosner. Her 1997 medical degree from the Uniformed Services University of the Health Sciences (USU) joins her residency at Walter Army Medical Center and a fellowship in urologic oncology at the National Cancer Institute.

Knowledge of prostate cancer has exploded in the two decades since Rosner became a doctor. Asked how the research boom has affected her practice, Rosner has a surprising answer.

“It’s gotten a little harder,” Rosner said. “Prostate cancer is unlike other cancers; there [are] different stages of disease and varying degrees of aggressiveness.” That complexity creates a wide array of treatment choices for patients, she explained.



Army Col. (Dr.) Inger Rosner, director of the Center for Prostate Disease Research, scans research data at her office at Walter Reed Bethesda, where she also serves as director of the Urologic Oncology Service. (Photo by Paula Amann)

Rosner wears several professional hats. She is director of Urologic Oncology at Walter Reed Bethesda, where she sees patients at the Center for Prostate Disease Research and the Urology Service. Rosner also directs CPDR and its clinical research. Meanwhile, she serves as assistant professor of surgery at USU.

Some of Rosner’s research strives to “translate” developments in basic science into clinical practice. With Jennifer Cullen, she led a 2015 study of 402 patients that supported use of the 17-gene Genomic Prostate Score to predict the aggressiveness of prostate tumors.

Her scholarship also touches on quality of life in patients diagnosed and treated for prostate cancer. Rosner was part of a team of researchers led by Dr. John Banerji and

Lauren Hurwitz that looked at health-related quality-of-life outcomes among patients with low-risk cancers.

Patients treated with external-beam radiation therapy suffered declines in bowel quality of life, compared with those managed simply with active surveillance, the researchers found. Their study appeared in the May issue of Urologic Oncology.

Such projects all add up to new knowledge that can help men with prostate cancer sort through the full range of treatments available – from active surveillance to surgery.

“The goal here on the clinical side is to educate patients and empower them to make good decisions, because they have lots of options,” Rosner said. □

Writing Rx

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RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) invites you to the Research Roundtable on the third Tuesday of most months. Our new program includes a 15-minute presentation on a “how to” research topic, followed by 45 minutes of questions and answers about challenges with conducting research, navigating the Electronic Institutional Review Board or submitting actions to the Institutional Review Board.

At the next roundtable on Oct. 17, **Diane Beaner**, a research compliance officer in our department, will speak on the topic, “**Non-Compliance in Human Subjects Research.**” We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to lead a discussion on a research-related topic, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil.

Meanwhile, I would like to join your team to provide a 10-15 minute update on DRP services annually or every six months, before or after your program meets for didactic or lecture hall sessions. These remarks range from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF), and information on required Collaborative Institutional Training Initiative (CITI) training.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements. Our services include assistance with protocol development; courses on research methods, statistics and writing; GME trainee research project funding; collaborative agreement development; manuscript editing; publication clearance and bench research space through our Biomedical Research Laboratory.

I hope to see you soon at one of our events! ☐



Lisa Thompson,
academic research
education specialist
(Photo by subject)

Managing multiple stipulations with ease Roogow offers guidance on Electronic Institutional Review Board

Stipulations, or required changes in submissions to the Electronic Institutional Review Board, can flummox EIRB users.

At a Research Roundtable on Sept. 25, Robert Roogow, director of IRB operations, furnished some pointers on handling more than one stipulation:

- When addressing multiple stipulations for a single document, you can revise the document in the first stipulation and include all of the revisions required by the multiple stipulations.
- Once one of the stipulations has the revised document associated with it, complete the other stipulations without creating another version of the document.



Robert Roogow, director of Institutional Review Board operations, makes a point at the Sept. 25 Research Roundtable.
(Photo by Paula Amann)

- Click the “Stipulation Has Been Completed” button on the other stipulations. Then choose Yes, No, or N/A as appropriate.
- Then enter a note that states the stipulation was corrected in the other identified stipulation.
- After checking that all stipulations for a document are complete, finish the original stipulation as listed above.

Clear reasons for changes can help speed a submission, Roogow told the roundtable audience.

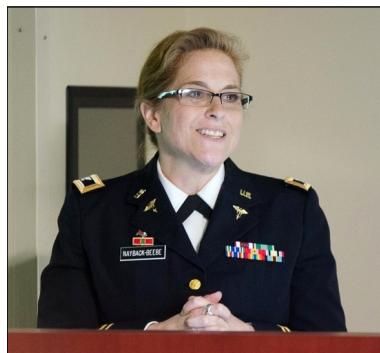
“The better the explanation, the easier it is for protocol analysts to understand what you’re trying to do,” Roogow said. ☐

To learn more, find slides from this talk at this [link](#).



Nayback-Beebe demystifies Data Safety Monitoring Board

Clinical trials of new drugs or devices offer promise for advances in health care but can also bring a measure of risk to the people who take part. That heightened risk can necessitate regular oversight of study data by a Data Safety Monitoring Board, an independent group of experts who monitor treatment effectiveness and patient safety.



Army Col. Ann Nayback-Beebe explained the role of the Data Safety Monitoring Board works at a Lunch and Learn Sept. 13. (Archival photo by John Fadoju)

On Sept. 13, Army Col. Ann Marie Nayback-Beebe explained the purpose and practice of the DSMB, as part of the series, Lunch and Learn: Research 2.0. She urged her audience to bring her message back to their research teams.

Nayback-Beebe encouraged attendees to educate other members

of the research community, so they fully understand the purpose and function of the DSMB – as well as why the

Institutional Review Board might require its oversight in certain circumstances.

A medical study requires monitoring by a DSMB in the following cases, she said:

- All Phase III clinical trials
- Some Phase I and Phase II clinical trials in certain cases:
 - ◊ Multiple sites
 - ◊ Blinded study
 - ◊ High-risk intervention
 - ◊ Vulnerable population
 - ◊ High likelihood of ending trial for safety or efficacy

In the end, the role of the DSMB revolves around the welfare of human subjects and their loved ones.

“At the center of all that research is the patient and the family behind them,” said Nayback-Beebe. □

To learn more, find slides from this talk at this [link](#).

Trio from Henry Jackson Foundation describes services

Three staff members from the Henry M. Jackson Foundation presented their work to researchers on Sept. 19, as part of the series, Lunch and Learn: Research 2.0.

Leading the team, Sheara Fewell, a technical advisor with the Research Initiatives Office, reviewed HJF’s services from proposal development through compliance checks.

Authorized as a nonprofit by a 1983 act of Congress, HJF aims to further military medical research, support the Uniformed Services University of the Health Sciences and bridge the military-civilian divide.

Locally, Fewell noted, HJF underwrites 1,005 staff members at the Uniformed Services University and another 134 at Walter Reed National Military Medical Center. The



Sheara Fewell, technical advisor with the Research Initiatives Office at the Henry Jackson Foundation, presents at a Sept. 19 Lunch and Learn: Research 2.0. (Photo by John Fadoju)

including help securing approval from the Institutional Review Board and negotiating cooperative research and development agreements.

“It takes a long time to get a protocol approved, with good reason,” said Norman Gardner, HJF’s director of clinical trials. “We’re there to make sure we don’t hold things up on our end, so that questions get answered right away.”

For such trials, HJF has developed a reloadable debit card which supports patients who take part in certain research studies. □

To learn more, find slides from this talk at this [link](#).



Mittman touts implementation science to boost health care

As economics and politics drive health care leaders and providers to seek higher-quality patient care at a more affordable price, research can help, said Brian Mittman in a Sept. 7 talk at Walter Reed National Military Medical Center.



Brian Mittman, research scientist at the Kaiser Permanente Department of Research and Evaluation, speaks Sept. 7 at Walter Reed Bethesda.
(Photo by John Fadoju)

The Department of Research Programs cohosted the event with the Health Services Research Program at Uniformed Services University of the Health Sciences.

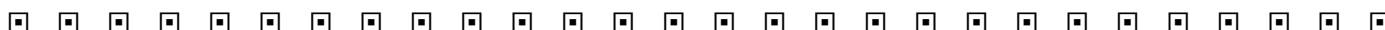
A research scientist at the Kaiser Permanente Department of Research and Evaluation, Division

of Health Services Research and Implementation Science, Mittman pointed to two kinds of translational research. One helps turn basic science into clinical research. The other, also known as implementation science, turns clinical research into better health processes and outcomes.

Mittman called for “a learning health system.” He argued that use of implementation science by health care leaders is “not a cost but ultimately a benefit.”

The speaker also co-leads the UCLA Clinical and Translational Science Institute’s Implementation and Improvement Science Initiative, and works with the U.S. Department of Veterans Affairs (voluntary role) and RAND Health Program. In addition, he chaired the committee that founded the journal, Implementation Science.

To learn more, find slides from this talk at this [link](#).



DARNALL MEDICAL LIBRARY **Research and Scholarly Communication Support**

Lyubov Tmanova offers research support to Walter Reed Bethesda’s medical community, leading research-oriented classes on a quarterly basis. Individual and group consultations are also available upon request.

Research and Scholarly Communication Classes ▪ Building 1, Room 209

Preparing Your Manuscript for Publication

Wednesday, Oct. 18, 12 p.m. ▪ Building 1, Room 209

Instructor: Dr. Lyubov Tmanova

This lecture is centered on planning, writing, and submitting manuscripts for publication in biomedical journals. The writing section of the lecture is centered on writing a compelling manuscript (title, abstract, introduction, methods, materials, results, and discussion). The manuscript submission process and review, journal selection, authorship guidelines and standards, copyright issues, research integrity, and DoD public access policy compliance will also be discussed.

Research Data Management

Wednesday, Oct. 25, 12 p.m. ▪ Building 1, Room 209

Instructor: Dr. Lyubov Tmanova

This lecture introduces a concept of data-driven research, research data management, and data management planning for grant proposals. The research data life cycle, including data collection, processing methods, and analysis of qualitative and quantitative data will be discussed. Attendees will become familiar with data submission standards and DoD biomedical research and data policy.

Medical Genetics Resources I

Wednesday, Nov. 1, 12 p.m. ▪ Building 1, Room 209

Instructor: Dr. Lyubov Tmanova

This lecture describes the National Center for Biotechnology Information molecular databases centered on medical genetics and genetic tests and laboratories.



DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

Hail and Farewell comes to monthly staff meeting

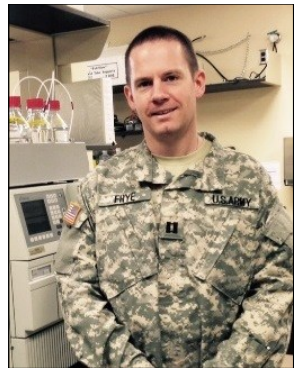
Navy Cmdr. Robert Liotta, the director of the Education, Training and Research Directorate, brought his traveling Hail and Farewell to the Department of Research Programs (DRP) at its monthly meeting on Sept. 7. Liotta welcomed his new deputy director, **Cmdr. Ruben Acosta**, along with several other staff members.



Navy Cmdr. Robert Liotta, director of the Education, Training and Research Directorate, visits the DRP monthly meeting Sept. 7. Liotta bid farewell to departing staff members and welcomed new ones. (Photo by Paula Amann)

Army Col. Peter Weina, DRP chief, used the occasion to pay tribute to recently retired **Dr. Wendy Bernstein**, who led scientific review for several years, and to **Army Capt. Franz Frye**, the outgoing chief of the Biomedical Research Laboratory. Franz, a prior assistant professor of chemistry at Concord College, looked back on his two years at the lab, which was his first duty assignment since joining the Army. “I learned an awful lot,” Frye said, noting new skills such as reviewing studies with human subjects. He will be putting his chemistry knowledge to work at the U.S. Army Research Laboratory.

For his part, Liotta exhorted the directorate staff to turn their attention to the progress they are making, rather than any challenges that may remain. “It’s a more exhilarating way to live,” Liotta said.



Army Capt. Franz Frye, former chief of the Biomedical Research Laboratory (Archival photo in the laboratory)

New, retooled events showcased

Army Col. Ann Nayback-Beebe, DRP deputy director, highlighted efforts to make the department’s educational programs more relevant to the concerns of researchers. First, the department has rolled out Lunch and Learn: Research 2.0, a twice-monthly education series with 45-minute presentations on research topics. Those dealing with human research protection may help participants earn continuing education credits for the Minimum Educational Research Framework.

Calling the new series “relevant education for all our customers, which includes principal investigators and other members of their research team, DRP staff, and IRB members,” Nayback-Beebe urged all Lunch and Learn attendees to sign in and complete feedback sheets, as an aid to speakers and to series planners.

The Research Roundtable, meanwhile, will return to its roots as a forum for discussion. In practice, this change will mean limiting formal “how to” presentations to roughly 15 minutes and using the rest of the hour for questions from researchers. We encourage all research team members to attend. Members of the DRP leadership team will be on hand to answer policy-related questions and address concerns from the research community.

Processing protocols, minding manners and pumping iron

Weina cited recent statistics that showed the time needed to process research protocols fell from 150-200 days in February-March of this year to the current 90 days. “Everyone has worked really hard to make that happen,” Weina said. “I’m really proud of what you guys have accomplished.”

The DRP chief also urged his staff to mind their email etiquette and communicate face-to-face in case of misunderstandings. “It’s never good to blindside someone,” Weina said. “It’s about treating people the way you want to be treated.”

On the human resources front, Weina flagged rules issued in September 2016 on exercise at work by full-time employees of up to three hours weekly. Among other points noted, supervisors must approve the exercise plan, employees must fill out a form, and employees must report to work before and after exercise.



FACES OF RESEARCH

ARRIVAL GATE

A biochemist by training, **Army Major Karen Thomas** recently joined the Department of Research Programs as chief of the Biomedical Research Laboratory. Prior to arriving here, Thomas served as Deputy Commander for Operations at the Forensic Toxicology Drug Testing Laboratory at Ft. George Meade, a job that entailed oversight for some 800,000 specimens annually.

Over several months in 2015, she was chief of the Biochemistry Laboratory at Camp Arifjan in Kuwait. Earlier, she served as the chief of the Core Laboratory directing chemistry and hematology services for Walter Reed Army Medical Center. In this role, she led the move of the hospital's clinical chemistry section to the new Walter Reed National Military Medical Center.

Thomas earned her bachelor's degree in microbiology at the University of Maryland in College Park. She went on to obtain a master's degree in biochemistry there. A veteran researcher, Thomas has been a named author on 20 studies in such scientific publications as the Journal of Immunology.



Army Major Karen Thomas, the new chief of the Biomedical Research Laboratory (Photo by Paula Amann)



The Department of Research Programs presents

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Time slot: First & Third Mondays 1200–1300

Month	Dates <i>Radiology Conference Room B015, Building 19, Basement</i>
October	2 16
November	6 20
December	4



RESEARCH POLICY RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked websites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

- [Belmont Report](#)
The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.
- [Comparison of FDA and HHS Regulations](#)
The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.
- [The President's Council on Bioethics](#)
This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.
- [Clinical Trials.gov](#)
Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.
- [HHS Office for Human Research Protections](#)
HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.
- [HHS Office of Civil Rights](#)
HHS Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).
- [MedlinePlus](#)
MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.
- [Office for Human Research Protections \(OHRP\)](#)
OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.
- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)
HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.
- [Protocol Review](#)
HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.
- [Informed Consent](#)
*HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to **documentation**.*
- [Vulnerable Populations](#)
HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)
- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)
- [Preambles to GCP Regulations](#)
- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)
- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)
- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)
- [Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products \(21 CFR Parts 50 and 56\)](#)
- [Informed Consent Elements \(21 CFR 50.25\(c\)\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)
- [Financial Disclosure by Clinical Investigators \(21 CFR Part 54\)⁸](#)
- [Institutional Review Boards \(21 CFR Part 56\)⁹](#) □

See RESOURCES, page 12



RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

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The Department of Research Programs presents

RESEARCH ROUNDTABLE

A forum for the research community



Topic: “Non-Compliance in Human Subjects Research”

Diane Beaner, Research Compliance Officer

Department of Research Programs

Tuesday, Oct. 17, 1200-1300

Executive Conference Room 0301, Building 9

Brown bag lunches welcome. Bring your questions on research compliance. All are invited!

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A twice-monthly education series for researchers

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CONSIDERATIONS IN PRAGMATIC CLINICAL TRIALS
(WEBINAR BY PRIM&R)

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INTRODUCTION TO TECHNOLOGY TRANSFER
MARTIN HINDEL, RESEARCH ATTORNEY



*Brown bag lunches welcome.
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